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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,275	03/14/2001	Randall W. Nelson	41821.0237	4255

20322 7590 10/24/2003

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EXAMINER	
COUNTS, GARY W	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 10/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Restarted on 10/24/03

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/808,275	03/14/2001	Randall W. Nelson	530-013	4255

7590 02/24/2003

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EXAMINER	
COUNTS, GARY W	
ART UNIT	PAPER NUMBER
1641	6

DATE MAILED: 02/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/808,275	Applicant(s) NELSON ET AL.	
	Examiner Gary W. Counts	Art Unit 1641	

-- The MAILING DATE of this communication app ars on the cov r sh t with the corr spondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *31-47* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31-47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the claims

The amendment filed January 24, 2003 is acknowledged and has been entered.

Specification

The use of the trademark Lumonics HY 400 has been noted in this application on page 41. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Double Patenting

1. Claims 31, 36 and 41 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of copending Application No. 09/808314. Although the conflicting claims are not identical, they are not patentably distinct from each other because it would have been obvious to one of ordinary skill in the art to determine and identify the analyte by using mass spectrometery for molecular weight analysis.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 31, 32, 36, 37, 41 and 45-47 are rejected under 35 U.S.C. 102(a) as being anticipated by Nelson et al (Mass Spectrometric Immunoassay, Analytical Chemistry 1995, 67, 1153-1158).

Nelson et al disclose a method to determine an analyte by capturing and isolating an antigen. Nelson et al disclose incubating antibodies covalently immobilized to a solid support with an antigen-containing sample. Nelson et al disclose that after incubation and the formation of antibody/antigen complexes (post-combination affinity reagent), the complexes are washed and then the antigen is eluted onto a mass spectrometer probe tip using a solution of MALDI matrix. Nelson et al. further disclose that after the antigen is eluted that Time-of-flight mass spectrometry is performed (page 1153 col 2, see also Experimental Section). Nelson et al also disclose that a single assay can be used to screen biological systems for the presence of multiple, mass-resolved antigens. Nelson et al also disclose that antigen signals are observed at characteristic mass-to-charge values in the mass spectrum. Nelson et al also disclose a plurality of antibodies on a solid substrate (Experimental Section). Nelson et al also

disclose that the affinity reagent-antigen complex is retained in a filter pipette tip (Figure 1 and description of Figure 1).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. Claims 34, 39 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Papac et al (Direct analysis of Affinity-Bound analytes by MALDI/TOF MS, Analytical Chemistry 194, 66, 2609-2613).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose adding a disassociation agent to the isolated post-combination affinity reagent prior to the step of adding the laser desorption/ioniztion agent.

Papac et al disclose sample preparation can influence the spectra observed and that for immobilized affinity chromatography, a 3 times stronger signal is observed when the supernatant is used for analysis (a dissociation reagent is used before application of the desorption/ionization agent) compared with mixing the MALDI matrix with the beads on the target (p. 2613, 3rd paragraph) and that immobilized affinity chromatography differs from conventional chromatography in that it exploits specific biological interactions such as those of an antibody and antigen which demonstrate high

specificity associated affinity binding and that, either half of a biological interaction can be used in the stationary phase as an immobilized ligand (p. 2609, paragraph 1).

It would have been obvious to one of ordinary skill in the art to incorporate the use of a dissociation reagent as taught by Papac et al into the method of Nelson et al because Papac et al show that this dissociation reagent allows for a 3 times stronger signal.

6. Claims 33, 38, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Raybuck et al (US Patent 5,833,927).

See above for teachings of Nelson et al.

Nelson et al differ from the instant invention in failing to disclose a filter element to which the affinity reagent is bound.

Raybuck et al disclose a micropipette tip comprising a porous membrane, which can act as a filter and also has antibodies bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate the substitute the membrane (filter) of Raybuck et al for the filter of Nelson et al because Raybuck et al shows that this membrane provides for a device for capturing a

component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

7. Claims 35, 40 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nelson et al in view of Papac et al as applied to claims 31, 32, ,34, 36, 37, 39, 41 and 43 above, and further in view of Raybuck et al.

See above for teachings of Nelson et al and Papac et al.

Nelson et al and Papac et al differ from the instant invention in failing to disclose a filter element to which the affinity reagent is bound.

Raybuck et al disclose a micropipette tip comprising a porous membrane which can act as a filter and also has antibodies bound to the surface for capturing the corresponding analyte (col 5, lines 30-59). Raybuck et al disclose that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment (col 6, lines 26-32).

It would have been obvious to one of ordinary skill in the art to incorporate the substitute the membrane (filter) of Raybuck et al for the filter of Nelson et al because Raybuck et al shows that this membrane provides for a device for capturing a component present in a fluid and provides the advantage of capturing the desired component on or at or in the forward-facing surface of the membrane thus allowing for easy access for subsequent treatment.

Response to Arguments

8. Applicant's arguments filed January 24, 2003 have been fully considered but they are not persuasive.

Applicant argues that the Nelson et al reference cited by the Examiner does not constitute a description of the invention in a printed publication before the invention was made by Applicants in that Applicants are the authors of the journal article, and Applicants conceived their invention before the publication of the Nelson et al reference. This is not found persuasive because Applicant has not submitted a declaration that demonstrates that Allan L. Bieber did not take part in the conception of the subject matter disclosed and claimed in the instant patent application, nor did Applicant disclose the work performed by Allan L. Bieber in connection with the instant reference. Therefore, the statement that Applicants are the authors of the journal article and Applicants conceived their invention before the publication of the Nelson et al reference is not found persuasive.

Applicant further argues that the Nelson et al reference does not constitute prior art for purposes of the Examiner's 35 U.S.C. Sec. 103(a) rejections because the Nelson et al reference was authored by the inventors and the inventors conceived the invention prior to the publication. This is not found persuasive because of reasons stated above. Therefore, it is the Examiner's position that since the Nelson et al reference still stands, the reference does constitute art for the purposes of the Examiner's 35 U.S.C Sec 103(a) rejections and it would have been obvious to arrive at Applicant's claimed

invention. Therefore the combination of the Nelson et al reference with the secondary references is appropriate and still stands for reasons of record.

Conclusion

9. No claims are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (703) 305-1444. The examiner can normally be reached on M-F 8:00 - 4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (703) 305-3399. The fax phone numbers for

the organization where this application or proceeding is assigned are (703)308-4242 for regular communications and (703)3084242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gary W. Counts
Examiner
Art Unit 1641
February 21, 2003

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
02/21/03